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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/756,125 01/09/01 KISHIMOTO

T 053466/0296

EXAMINER

HM12/0320

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ART UNIT	PAPER NUMBER
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DATE MAILED: 1644

03/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

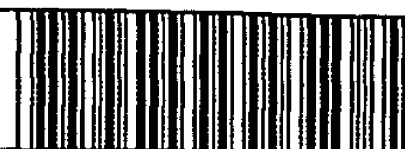
Office Action Summary

Application No.
09/756,125

Applicant(s)
Kishimoto et al

Examiner
F. Pierre VanderVegt

Group Art Unit
1644



☒ Responsive to communication(s) filed on Jan 9, 2001

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 9-17 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 9-17 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☒ received in Application No. (Series Code/Serial Number) 08/817,084.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to Comply with the Sequence Rules

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application is a divisional of application serial number 09/233,474, which is a divisional of application S.N. 08/817,084, which is a 371 of PCT/JP95/01144, and is a continuation-in-part of application S.N. 08/971,997, which is a continuation of application S.N. 08/268,520.

Claims 1-8 have been canceled. New claims 9-17 have been added and are currently pending in this application.

Specification

1. The disclosure is objected to because of the following informalities:

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

The specification discloses nucleotide sequences, for example, at line 23 of page 14 in the written specification. Regardless of whether nucleotide and/or amino acid are specifically claimed in the instant application or not, 37 CFR 1.182(c, d and e) put forth a clear requirement for each sequence to be identified by a SEQ ID NO and be represented both in computer readable form (CRF) and on the paper copy corresponding to the CRF. Applicant must provide an initial CRF, a corresponding paper copy and a new statement that the content of the CRF and the paper copy are the same and that they contain no new matter. See MPEP 2422.03-2422.04.

The claims should read in the form of a complete sentence beginning with "I/We claim" or "What is claimed is" and ending with a period. It is suggested that the word "CLAIMS" at the top of page 26 in the specification be replaced with --We claim-- or --What is claimed is--.

Appropriate correction is required.

Claim Objections

2. Claim 13 is objected to because of the following informalities: the claim is an independent claim but begins with the recitation "The method." The claim would read more properly if it began --A method--.

5 Appropriate correction is required.

Double Patenting

10 The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

15 A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

20 Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 9-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,888,510 to Kishimoto et al (A4 on form PTO-1449). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims drawn to methods using a
25 monoclonal antibody identified only by the laboratory designation PM-1 constitute anticipatory species of the invention claimed in the '510 patent. Further, the '810 patent discloses the use of said PM-1 antibody in exemplification of the claimed method.

Claim Rejections - 35 U.S.C. § 112

30 4. Claims 9-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The monoclonal antibody (mAb) recited in claims 9, 10, 13 and 15 is essential to the claimed invention. While the production of mAbs to the same antigen may be routine in the art, the reproduction of specific antibodies is an extremely unpredictable event. The PM-1 hybridoma, disclosed on page 18 of the specification, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the hybridoma, and it is not apparent if the hybridoma is readily available to the public. If a deposit of the hybridoma cell line has been made under the terms of the Budapest Treaty, an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the hybridoma cell line has been deposited under the Budapest Treaty and that the hybridoma will be **irrevocably** and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample **or for the enforceable life of the patent**, whichever is longer. See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from Applicant

to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the Applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

5. Claims 9-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

It is indefinite and ambiguous to recite the laboratory name "PM-1" in claims 9, 10, 13 and 15 to identify the mAb used in the claimed method. The same designation may be used by others as well to designate different mAbs. It is suggested that the corresponding accession or deposit number from an acceptable depository be recited in the claim.

Conclusion

6. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2001 365-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
March 16, 2001

